

Listing of Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Complete Listing of Claims:

1. (Previously presented) A method of preventing or delaying onset of Type 1 diabetes in a subject in need thereof, the method comprising administering to the subject a pharmaceutically acceptable composition comprising a soluble fusion protein, wherein the fusion protein comprises at least one immunoglobulin having a variable region comprising a CDR1, a CDR2, or a CDR3 region, the at least one immunoglobulin having at least one protein fragment or peptide inserted within the variable region; wherein (a) the protein fragment or peptide is GAD2 represented by SEQ. ID NO 4, (b) the subject has undergone insulin autoantibody seroconversion prior to said administering step and (c) the composition is administered to the subject in one or more dosage administrations.
2. (Original) The method of claim 1, wherein the immunoglobulin is human or humanized.
3. (Previously presented) The method of claim 1, wherein the subject is a human subject.
4. (Previously presented) The method of claim 1, wherein administration of the composition to the subject results in down regulation of an autoreactive T cell.
5. (Previously presented) The method of claim 1, wherein the at least one protein fragment or peptide is inserted within a CDR region of the at least one immunoglobulin.
6. (Cancelled)
7. (Previously presented) The method of claim 5, wherein administration of the composition to the subject results in substantially reduced activation of an autoreactive T cell specific for the at least one protein fragment or peptide.

8. (Withdrawn) The method of claim 1, wherein the at least one protein fragment or peptide is derived from INS.
9. (Withdrawn) The method of claim 8, wherein the INS comprises soluble INS β .
10. (Withdrawn) The method of claim 9, wherein the soluble INS β is capable of binding to at least one Fc receptor.
11. (Withdrawn) The method of claim 10, wherein the Fc receptor is a Fc γ receptor.
12. (Withdrawn) The method of claim 10, wherein the composition is capable of being endocytosed by antigen presenting cells.
13. (Previously presented) The method of claim 1, wherein the at least one protein fragment or peptide consists essentially of GAD2 represented by SEQ. ID NO 4.
14. (Cancelled)
15. (Previously presented) The method of claim 13, wherein the subject is GAD positive.
16. (Previously presented) The method of claim 1, wherein the subject has not developed hyperglycemia at initiation of the administering step.
17. (Previously presented) The method of claim 1, wherein the subject expresses a Type 1 diabetes predisposition marker at initiation of the administering step.
18. (Previously presented) The method of claim 1, wherein upon administration of the composition to the subject, the subject undergoes a dose dependent suspension, prevention, or delay in onset of Type 1 diabetes.
19. (Previously presented) The method of claim 1, wherein administration of a first dosage of the composition occurs before the subject has developed type-1 diabetes.
20. (Withdrawn) A composition for suppressing the onset of Type 1 diabetes in a subject that has undergone IAA seroconversion, the composition comprises: a pharmaceutically acceptable composition comprising at least one immunoglobulin selected from the group

consisting of INS, GAD, an insulin protein, a peptide derived from insulin, a diabetogenic epitope, and a T cell receptor engaging determinant.

21. (Withdrawn) The method of claim 20 wherein the fusion protein is in soluble form.
22. (Previously presented) The method of claim 2 wherein the immunoglobulin is selected from the group consisting of IgG1, IgG2, IgG2a, IgG2b, IgG3, IgG4, IgGA, IgA1, IgA2, IgGE, IgD, IgE, or IgM.
23. (Previously presented) The method of claim 5 wherein the at least one protein fragment or peptide is inserted within the CDR3 region of the immunoglobulin.
24. (Previously presented) The method of claim 23 wherein the at least one protein fragment or peptide is inserted within the CDR3 region of the immunoglobulin in place of a D segment.
25. (Previously presented) The method of claim 13 wherein the at least one protein fragment or peptide consists of amino acid residues 524-543 of GAD65.
26. (Previously presented) The method of claim 13 wherein the at least one protein fragment or peptide consists of amino acid residues 206-220 of GAD65.
27. (Original) The method of claim 13 wherein the subject is a human.
28. (Original) The method of claim 1 wherein the pharmaceutical composition further comprises at least one pharmaceutically acceptable carrier.
29. (Original) The method of claim 28 wherein the composition comprises an aqueous solution or suspension.
30. (Original) The method of claim 29 where the administering step is accomplished by injection or infusion.